

§ 158.603 Notice to responsible entities.

If HHS learns of a potential violation described in § 158.602 of this subpart or if a State informs HHS of a potential violation prior to imposing any civil monetary penalty HHS must provide written notice to the issuer, to include the following:

- (a) Describe the potential violation.
- (b) Provide 30 days from the date of the notice for the responsible entity to respond and to provide additional information to refute an alleged violation.
- (c) State that a civil monetary penalty may be assessed if the allegations are not, as determined by HHS, refuted.